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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,516	05/26/2006	Staffan Stromblad	P07900US01/BAS	4509

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STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,516	STROMBLAD ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 6-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 2/27/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 3-5 were rejected under 35 U.S.C. 103(a) as being obvious over BYKOV, et al (see PTO-892 dated 12/04/2007), in view of Hartmann et al (see PTO-892 dated 12/04/2007).

This rejection is maintained.

Examiner rejected the claims on the basis that BYKOV et al teaches 2,2-bis(hydroxymethyl)quinuclidin-3-one (claim 2) for the treatment of human tumors (page 12 lines 3-5) by reactivating the apoptosis-inducing function of p53 (page 11, lines 1-6) where the compound is the same as the elected compound (see Election/Restrictions section above). Further, the compound may be used in pharmaceutical compositions (page 11, lines 10-13). BYKOV et al does not specifically disclose treatment of malignant melanoma. Hartmann et al teaches inactivated p53 is present in malignant melanoma cells (see page 315, discussion). Therefore, one skilled in the art would find it obvious to apply the teaching of BYKOV et al to use 2,2-bis(hydroxymethyl)quinuclidin-3-one to treat human tumors which contain inactivated

p53, including malignant melanoma as taught by Hartmann et al. Applying these teachings, one skilled in the art would find the instantly claimed method obvious.

Applicants argue amended claim 5 includes language that requires the compound of claim 5 as being capable of transferring wild type p53 from an inactive conformation into an active confirmation capable of inducing apoptosis. Applicants argue Bykoc only discusses mutant type p53 and Hartman discusses the predominance of wild type p53 in malignant melanoma. Therefore there would be not motivation to combine.

First, with regards to motivation to combine, Hartmann was only cited to illustrate that malignant melanoma is a cancer with wild type p53. Cells which have mutant type p52 will must necessarily have wild type p53. Therefore, it would be obvious to one of ordinary skill in the art to treat a patient with multiple melanoma, where wild type p53 is present, with a compound reactivates the apoptosis-inducing function of wild type p53.

Second, the language of instant claim 5 is such that the compound only is required to be “capable” of transferring wild p53 from an inactive conformation to an active confirmation which is capable of inducing apoptosis. Where the compound previously disclosed is the same as instantly disclosed, it must necessarily have that capability.

Double Patenting

Claims 3-5 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,921,765, in view of Hartmann et al (cited above).

This rejection is maintained.

US Patent No. 6,921,765 claims the treatment of "cancer", whereas the current application claims treatment of "malignant melanoma". Hartmann et al teaches malignant melanoma is a form of cancer (see page 316). One skilled in the art would find it obvious to apply the cancer treatment method of US 6,921.765 to specific cancers, such as malignant melanoma.

Hartmann was only cited to illustrate that malignant melanoma is a cancer with wild type p53. Therefore, it would be obvious to one of ordinary skill in the art to recognize that when treating the broad scope of “cancers” using the disclosed compound, malignant melanoma may be chosen due to the presence of wild type p53. Where the compound previously disclosed is the same as instantly disclosed, it must necessarily have that capability.

Claims 3-5 were provisionally rejected on the ground of nonstatutory obviousness- type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/590,054 in view of Hartmann et al (cited above).

This rejection is maintained.

Claims 1-2 of copending Application No. 10/590,054 claim the treatment of "cancer", whereas the current application claims treatment of "malignant melanoma".

Hartmann et al teaches malignant melanoma is a form of cancer (see page 316). One skilled in the art would find it obvious to apply the cancer treatment method of copending Application No. 10/590,054 to specific cancers, such as malignant melanoma.

This is a provisional obviousness-type double patenting rejection.

Again, Hartmann was only cited to illustrate that malignant melanoma is a cancer with wild type p53. Therefore, it would be obvious to one of ordinary skill in the art to recognize that when treating the broad scope of "cancers" using the disclosed compound, malignant melanoma may be chosen due to the presence of wild type p53. Where the compound previously disclosed is the same as instantly disclosed, it must necessarily have that capability.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-3:45 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Patent Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612